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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/44	A1	**(11) International Publication Number:** WO 00/07527 **(43) International Publication Date:** 17 February 2000 (17.02.00)

(21) International Application Number: PCT/EP99/05541

(22) International Filing Date: 30 July 1999 (30.07.99)

(30) Priority Data:

60/095,209	3 August 1998 (03.08.98)	US
PCT/EP99/05008	15 July 1999 (15.07.99)	EP

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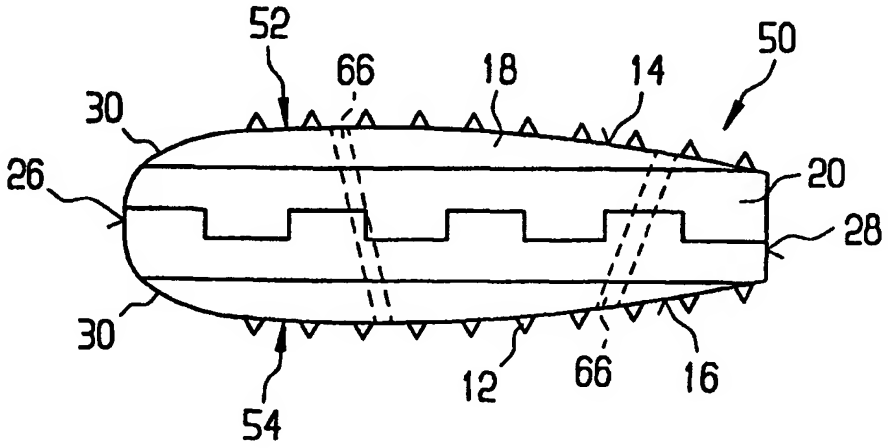
(81) Designated States: CA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: INTERVERTEBRAL ALLOGRAFT SPACER



(57) Abstract

An allogenic implant (10; 40; 50; 70), particularly an allogenic intervertebral implant (10; 40; 50; 70; 80) for fusing vertebrae is disclosed. The implant (10; 40; 50; 70; 80) is a piece of allogenic bone conforming in size and shape with portions of end plates of a vertebrae. The implant (10; 40; 50; 70; 80) has a wedge-shaped profile to restore disc height and the natural curvature of the spine. The top and bottom surfaces (14; 16) of the implant have a plurality of teeth (12) to resist expulsion and provide initial stability. The implant (10; 40; 50; 70; 80) according to the present invention provides initial stability needed for fusion without stress shielding.

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INTERVERTEBRAL ALLOGRAFT SPACER

The present invention is directed to an allogenic implant according to the definition of claim 1. More particularly, it refers to an allogenic intervertebral implant conforming in size and shape with end plates of vertebrae.

A number of medical conditions such as compression of spinal cord nerve roots, degenerative disc disease, and spondylolisthesis can cause severe low back pain. Intervertebral fusion is a surgical method of alleviating low back pain. In posterior lumbar interbody fusion ("PLIF"), two adjacent vertebral bodies are fused together by removing the affected disc and inserting an implant that would allow for bone to grow between the two vertebral bodies to bridge the gap left by the disc removal.

A number of different implants and implant materials have been used in PLIF with varying success. Current implants used for PLIF include threaded titanium cages and allografts. Threaded titanium cages suffer from the disadvantage of requiring drilling and tapping of the vertebral endplates for insertion. In addition, the incidence of subsidence in long term use is not known. Due to MRI incompatibility of titanium, determining fusion is problematic. Finally, restoration of lordosis, i.e., the natural curvature of the lumbar spine is very difficult when a cylindrical titanium cage is used.

Allografts are sections of bone taken from a long bone of a donor. A cross section of the bone is taken and processed using known techniques to preserve the allograft until implantation and reduce the risk of an adverse immunological response when implanted. For example, U.S. Patent No. 4,678,470 discloses a method for processing a bone grafting material which uses glutaraldehyde tanning to produce a non-antigenic, biocompatible material. Allografts have mechanical properties which are similar to the shielding that occurs with metallic implants. They are also MRI compatible so that fusion can be more accurately ascertained and promote the formation of bone, i.e., osteoconductive. Although the osteoconductive nature of the allograft provides a biological interlocking between the allograft and the vertebrae for long term mechanical strength, initial and short term mechanical strength of the interface between the allograft

and the vertebrae are lacking as evidenced by the possibility of the allograft being expelled after implantation.

Currently commercially available allografts are simply sections of bone not specifically designed for use in PLIF. As a result, the fusion of the vertebral bodies does not occur in optimal anatomical position. A surgeon may do some minimal intraoperative shaping and sizing to customize the allograft for the patient's spinal anatomy. However, significant shaping and sizing of the allograft is not possible due to the nature of the allograft. Even if extensive shaping and sizing were possible, a surgeon's ability to manually shape and size the allograft to the desired dimensions is severely limited.

Most PLIF implants, whether threaded cages or allograft, are available in different sizes and have widths that vary with the implant height. For example, the width of a cylindrical cage will be substantially equivaltent with the implant height. Although larger heights may be clinically indicated, wider implants are generally not desirable since increased width requires removal of more of the facet, which can lead to decreased stability, and more retraction of nerve roots, which can lead to temporary or permanent nerve damage.

As the discussion above illustrates, there is a need for an improved implant for fusing vertebrae.

The invention solves the posed problem with an implant that shows the features of claim 1. Additional advantageous embodiments of the invention are characterized in the subclaims.

The present invention relates to an allogenic intervertebral implant for use when surgical fusion of vertebral bodies is indicated. The implant comprises a piece of allogenic bone conforming in size and shape with a portion of the end plates of the vertebrae and has a wedge-shaped profile with a plurality of teeth located on top and bottom surfaces. The top and bottom surfaces can be flat planar surfaces or curved surfaces to mimic the topography of the end plates. The implant has a channel on at least one side for receiving a surgical tool. This channel runs in the anterior direction to accommodate a

variety of surgical approaches. A threaded hole on the anterior, posterior, posterior-lateral, or lateral side can be provided for receiving a threaded arm of an insertion tool.

In another embodiment, the implant has an interior space for receiving an osteoconductive material to promote the formation of new bone.

In another embodiment, the implant is made in two halves: a top portion having a top connecting surface and a bottom portion having a bottom connecting surface. The top connecting surface mates with the bottom connecting surface when the top and bottom portions are joined. The top and bottom portions have holes that align for receiving a pin to secure the top and bottom portions together. The pin can be made of allogenic bone.

In yet another embodiment, the medial side of the implant has a scalloped edge such that when a first implant is implanted with a second implant with the medial sides facing each other, the scalloped edges define a cylindrical space.

The present invention also relates to a discrete spacer used in conjunction with any of the other embodiments of the implant. The spacer comprises a piece of allogenic bone conforming in size and shape with a portion of an end plates of the vertebrae and has a wege-shaped profile with substantially smooth top and bottom surfaces. The intersecting regions between the top and bottom surfaces and at least of the lateral sides and the intersecting region between the anterior and posterior sides and the same lateral side are curved surfaces to facilitate implantation of the spacer. Thus, the spacer can be implanted through an opening on one side of the spinal canal and moved with a surgical instrument to the contralateral side.

The invention and additional embodiments of the invention are explained in even more detail with reference to the partially schematic illustration of the embodiments.

In the drawings:

FIG. 1 is a top view of a first embodiment of the implant according to the present invention;

FIG. 2 is a side view of the implant of FIG. 1;

FIG. 3 is a back view of the implant of FIG. 1;

FIG. 4 is a top view of a second embodiment of the implant;

FIG. 5 is a side view of the implant of FIG. 4;

FIG. 6 is a top view of a third embodiment of the implant;

FIG. 7 is a side view of the implant of FIG. 6;

FIG. 8A is a top view of a top connecting surface of a top portion of the implant of FIG. 6;

FIG. 8B is a top view of a bottom connecting surface of a bottom portion of the implant of FIG. 6;

FIG. 9 is a perspective view of a fourth embodiment of the implant;

FIG. 10A is a side view of one embodiment of the teeth on the implant;

FIG. 10B is a side view of a second embodiment of the teeth of the implant,

Fig. 11 is a side view of an embodiment of the implant similar to the embodiment of Fig. 6 – 8;

Fig. 12 is a top view of a vertebral bone characteristic of those of the cervical, thoracic, or lumbar spine;

Fig. 13 is a side view of sequentially aligned vertebral bones, such as are found in the cervical, thoracic, or lumbar spine;

Fig. 14 is a posterior view of a sequence of vertebrae; and

Fig. 15 is an end view of another embodiment of the implant.

FIG. 1 shows a top view of a first embodiment of intervertebral allograft spacer or implant 10 according to the present invention. Implant 10 conforms in size and shape with a portion of end plates of the vertebrae between which implant 10 is to be implanted. Because implant 10 is an allograft, implant 10 promotes the formation of new bone to fuse the two vertebral bodies together. Although implant 10 will probably be predominantly used in the lumbar region of the spine, implant 10 can be configured for implantation in any region of the spine. Implant 10 has a plurality of teeth 12 on superior and inferior surfaces 14, 16 which provide a mechanical interlock between implant 10 and the end plates. Teeth 12 provide the mechanical interlock by penetrating the end plates. The initial mechanical stability afforded by teeth 12 minimizes the risk of post-operative expulsion of implant 10. Teeth 12 can be pyramid-shaped (FIG. 10A). Preferably, the angle formed from the tip to the base is approximately 60°. Alternatively, teeth 12 have a saw tooth shape with the saw tooth running in the anterior-posterior direction (FIG. 10B).

As shown in FIG. 2 and FIG. 3, a first lateral side 18 has a channel 20 and a second lateral side 22 also has a channel 20. Channels 20 are sized to receive a surgical instrument such as an inserter for implantation of implant 10. If the inserter has a threaded arm, implant 10 can be provided with a threaded hole 24. In FIG. 2, channel 20 is shown extended only partially along first lateral side 18. Channel 20 can extend along the entire length of first lateral side 18 as shown in the embodiment of FIG. 5. In FIG. 3, channels 20 are shown on both first and second lateral sides 18, 22. It should be noted that implant 10 can also have no channels or channels on one lateral side only as shown in the embodiment of FIG. 9.

The dimensions of implant 10 can be varied to accommodate a patient's anatomy. Typically, implant 10 would have a width between 6-15 mm (in the medial-lateral direction), a length between 15-30 mm (in the anterior-posterior direction), and a height between 4-30 mm (maximum height in the superior-inferior direction). The size of implant 10 allows implant 10 to be implanted using conventional open surgical

procedures or minimally invasive procedures, such as laparoscopic surgery. Additionally, because the width is kept to a restricted size range and does not necessarily increase with implant height, taller implants can be used without requiring wider implants. Thus, facet removal and retraction of nerve roots can remain minimal.

In order to restore the natural curvature of the spine after the affected disc has been removed, implant 10 has a wedge-shaped profile. As shown in FIG. 2, this wedge shape results from a gradual decrease in height from an anterior side 26 to a posterior side 28. In anatomical terms, the natural curvature of the lumbar spine is referred to as lordosis. When implant 10 is to be used in the lumbar region, the angle formed by the wedge should be approximately between 4,2° and 15° so that the wedge shape is a lordotic shape which mimics the anatomy of the lumbar spine.

In order to facilitate insertion of implant 10, anterior side 26 transitions to superior and inferior surfaces 14, 16 with rounded edges 30. Rounded edges 30 enable implant 10 to slide between the endplates while minimizing the necessary distraction of the endplates.

Although implant 10 is typically a solid piece of allogenic bone, implant 10 can be provided with a hollow interior to form an interior space. This interior space can be filled with bone chips or any other osteoconductive material to further promote the formation of new bone.

FIG. 4 shows a top view of a second embodiment of an implant 40 according to the present invention. In general, most of the structure of implant 40 is like or comparable to the structure of implant 10. Accordingly, discussion of the like components is not believed necessary. The superior and inferior surfaces 14, 16 of implant 10 are flat planar surfaces. As seen best in FIG. 5, superior and inferior surfaces 14, 16 of implant 40 are curved surfaces which still retain the wedge-shaped profile. The curved surfaces of superior and inferior surfaces 14, 16 of implant 40 are a mirror-image of the topography of the vertebral end plates. Thus, the curved surfaces conform to the contours of the end plates.

FIG. 6 shows a top view of a third embodiment of an implant 50 according to the present invention. In general, most of the structure of implant 50 is like or comparable to the structure of implants 10, 40. Accordingly, discussion of the like components is not believed necessary. As best seen in FIG. 7, implant 50 comprises a top portion 52 joined to a bottom portion 54. As it may be difficult to obtain a single section of allogenic bone from which implant 50 is to be made, fabricating implant 50 in two pieces, i.e. top and bottom portions 52, 54, allows smaller sections of allogenic bone to be used. A top connecting surface 56 and a bottom connecting surface 58 define the interface between top and bottom portions 52, 54. As shown in FIGS. 8A and 8B, top and bottom surfaces 56, 58 have ridges 60 that mate with grooves 62 to interlock top and bottom portions 52, 54. Preferably, ridges 60 and grooves 62 are formed by milling top and bottom surfaces 56, 58 in a first direction and then milling a second time with top and bottom surfaces 56, 58 oriented 90° with respect to the first direction.

A pin 64 passing through aligned holes 66 in top and bottom portions 52, 54 serves to retain top and bottom portions 52, 54 together. Although pin 64 can be made of any biocompatible material, pin 64 is preferably made of allogenic bone. The number and orientation of pins 64 can be varied.

Fig. 11 shows an embodiment of an implant 80 which, like implant 50, is made in multiple pieces. In general, most of the structure of implant 80 is like or comparable to the structure of implants 10, 40, 50. Accordingly, discussion of the like components is not believed necessary. Implant 80 has a top portion 82, a middle portion 84, and a bottom portion 86. As was the case for implant 80, the surfaces between the portions are mating surfaces with interlocking surface features, such as ridges and grooves. One or more pins preferably hold top, middle, and bottom portions 82, 84, 86 together.

FIG. 9 shows a perspective view of a fourth embodiment of a first implant 70 according to the present invention. A second implant 70', which is substantially similar to first implant 70, is also shown. In general, most of the structure of first and second implants 70, 70' is like or comparable to the structure of implants 10, 40, 50. Accordingly, discussion of the like components is not believed necessary. First lateral sides 18 of first and second implants 70, 70' are scalloped to have a C-shape. When first and second implants 70, 70' are placed side by side with the first lateral sides 18 facing

each other, a cylindrical space 72 is formed. When first and second implants 70, 70' are implanted together, cylindrical space 72 can be filled with osteoconductive material to help promote the formation of new bone. First and second implants 70, 70' can be provided with locking pins 74 which engage apertures 76 to maintain the spatial relationship between first and second implants 70, 70'.

The use of the implant according to the present invention will now be described with reference to Fig. 12 – 14 and using posterior lumbar interbody fusion as an example. As the implant according to the present invention conforms in size and shape to a portion of end plates 100, preoperative planning is recommended for proper sizing. Determine the appropriate implant height by measuring adjacent intervertebral discs 102 on a lateral radiograph. The implant must be seated firmly with a tight fit between end plates 100 when the segment is fully distracted. The tallest possible implant should be used to maximize segmental stability. Due to variability in degrees of magnification from radiographs, the measurements are only an estimate.

With the patient in a prone position on a lumbar frame, radiographic equipment can assist in confirming the precise intraoperative position of the implant. The surgeon incises and dissects the skin from a midline laterally and locates spinous process 104, lamina 106, dura 108, and nerve roots of the appropriate level(s). As much as possible facets 110 should be preserved to provide stability to the intervertebral segment. The surgeon performs a laminotomy to the medial aspect of facet 110 and reflects dura 108 to expose an approximately 13 mm window to the disc space. Disc 102 is removed through the window until only anterior 112 and lateral 114 annulus remain. The superficial layers of the entire cartilaginous end plates 100 are also removed to expose bleeding bone. Excessive removal of the subchondral bone may weaken the anterior column. Furthermore, if the entire end plate is removed, this may result in subsidence and a loss of segmental stability.

Distraction can be done with either a surgical distractor or a trial spacer implant. In the first method, the distractor blades should be completely inserted into the disc space so that the ridges at the end of the blades rest on vertebral body 116. Fluoroscopy can assist in confirming that the distractor blades are parallel to end plates 100. Correct placement will angle the handles of the distractor cranially, particularly at L5-S1. The

handle of the distractor is squeezed to distract the innerspace. The distraction is secured by tightening the speed nut on the handle.

Using the preoperatively determined size, a trial spacer is inserted in the contralateral disc space with gentle impaction. Fluoroscopy and tactile judgement can assist in confirming the fit of the trial spacer until a secure fit is achieved. Using either the slots or threader hole on the implant, the selected implant is inserted in the contralateral disc space. Alternatively, the channels on the implant allow distraction and insertion to occur on the same side. Regardless of the side the implant is inserted in, autogenous cancellous bone or a bone substitute should be placed in the anterior and medial aspect of the vertebral disc space prior to placement of the second implant. The distractor is removed and a second implant of the same height as the first implant is inserted into the space, using gentle impaction as before. Preferably, the implants are recessed 2 – 4 mm beyond the posterior rim of the vertebral body.

As previously noted, the implant according to the present invention can be inserted using minimally invasive procedures. In some of these procedures, only one side of the spinal cord needs to be approached. This minimizes muscle stripping, scar tissue in the canal, and nerve root retraction and handling. In clinical situations in which bilateral implant placement is required, proper implantation on the side opposite the incision can be difficult. Fig. 15 shows a beveled spacer 120 that facilitates placement on the side contralateral to the incision. In general and unless otherwise described, most of the structure of beveled spacer 120 is like or comparable to the structure of implants 10, 40, 50 and 80. Accordingly, discussions of the like components is not believed necessary. First lateral side 18 transitions to superior and inferior surfaces 14, 16 with rounded edges 30. First lateral side 18 also transitions to anterior and posterior sides 26, 28 with rounded edges 30. Additionally, spacer 120 has no teeth. The lack of teeth and rounded edge 30 enable spacer 20 to slide between the end plate and across the evacuated space (from one lateral annulus to the other) to the contralateral side. As first lateral side 18 is the side that must promote movement of spacer 120, the use of rounded edges 30 on second lateral side 22 is optionally. Once spacer 120 has been placed on the side contralateral to the single incision using a surgical instrument to push spacer 120, bone graft or other osteoconductive material is packed in the disc

space. Finally, an implant (any of implant 10, 40, 50, 70 or 70' can be used) is implanted in the side proximal to the incision.

While it is apparent that the illustrative embodiments of the invention herein disclosed fulfil the objectives stated above, it will be appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. Therefore, it will be understood that the appended claims are intended to cover all such modifications and embodiments which come within the scope of the present invention.

CLAIMS

1. An implant (10;40;50;70;80) comprising a piece of allogenic bone, characterized in that the implant (10;40;50;70;80) has a plurality of planar or curved sidewalls (18;22;26;28), a top surface (14) and a bottom surface (16) in order to fit as a graft between surfaces of adjacent bones or bone fragments.

2. The implant according to claim 1, characterized in that the implant (10;40;50;70;80) has a wedge-shaped profile.

3. The implant according to claim 1 or 2, characterized in that at least one sidewall (18;22;26;28) has a channel (20) for receiving a surgical instrument.

4. The implant according to claim 3, characterized in that the channel (20) runs in an anterior-posterior direction.

5. The implant according to one of the claims 1 to 4, characterized in that the top and bottom surfaces (14;16) of the implant (10;40;50;70;80) are provided with a three-dimensional structure for interlocking with adjacent surfaces of bones or bone fragments.

6. The implant according to claim 5, characterized in that the three-dimensional structure includes a plurality of teeth (12).

7. The implant according to claim 6, characterized in that the teeth (12) have a pyramid shape.

8. The implant according to claim 6, characterized in that the teeth (12) have a saw tooth shape.

9. The implant according to one of the claims 1 to 9, characterized in that at least one sidewall (18;22;26;28) of the implant (10;40;50;70;80) has at least one hole (24) for attachment of an inserter.

10. The implant according to claim 9, characterized in that the at least one hole (24) is threaded.

11. The implant according to claim 9 or 10, characterized in that the at least one hole (24) is provided in an anterior, posterior, posterior-lateral, or lateral side.

12. The implant according to one of the claims 1 to 11, characterized in that the top and bottom surfaces (14;16) are defined by flat planar surfaces.

13. The implant according to one of the claims 1 to 12, characterized in that a region between the top and bottom surfaces (14;16) and an anterior side of the implant is a curved edge (30) to facilitate implantation of the implant.

14. The implant according to one of the claims 1 to 13, characterized in that it is an intervertebral implant (10;40;50;70;80) conforming in size and shape with a portion of end plates of vertebrae.

15. The implant according to claim 14, characterized in that the top and bottom surfaces (14;16) are defined by curved surfaces, said curved surfaces contoured to mimic surfaces of the end plates of the vertebrae.

16. The implant according to one of the claims 1 to 15, characterized in that the implant (10;40;50;70;80) has an interior space (72) for receiving an osteoconductive material.

17. The implant according to one of the claims 1 to 16, characterized in that the implant (10;40;50;70;80) further comprises a top portion (52) having a top connecting surface (56) and a bottom portion (54) having a bottom connecting surface (58), the top connecting surface (56) mating with the bottom connecting (58) surface when the top and bottom portions (52;54) are joined.

18. The implant according to claim 17, characterized in that top and bottom connecting surfaces (56;58) are provided with ridges (60) and grooves (62) that mate with each other in order to interlock the top and bottom portions (52;54).

19. The implant according to claim 17 or 18, characterized in that a pin (64) is inserted through a hole (66) in the top portion (52) and a hole (66) in the bottom portion (54) to secure the top and bottom portions (52;54) together.

20. The implant according to claim 19, characterized in that the pin (64) is made of allogenic bone.

21. The implant according to one of the claims 1 to 20, characterized in that a medial side (18) of the implant (70;70') has a scalloped edge such that when a first implant (70) is implanted with a second implant (70') with the medial sides (18) of the first and second implant (70;70') facing each other, the scalloped edges of the medial sides (18) of the first and second implants (70;70') define a cylindrical space (72).

22. The implant according to claim 21, characterized in that the first implant (70') is provided with a locking pin (74) on the medial side (18) and the second implant (70) is provided with an aperture (76) at the medial side (18) configured and dimensioned to receive the locking pin (74) to maintain the spatial relationship between the first and second implants (70;70').

23. The implant according to claim 22, characterized in that the locking pin (74) is made of allogenic bone.

24. The implant according to one of the claims 1 to 23, characterized in that the implant (10;40;50;70;80) has a with between 6 – 15 mm.

25. The implant according to one of the claims 1 to 24, characterized in that the implant (10;40;50;70;80) has a length between 15 - 30 mm.

26. The implant according to one of the claims 1 to 25, characterized in that the implant (10;40;50;70;80) has a height between 4 - 30 mm.

27. The implant according to one of the claims 1 to 26, characterized in that the implant (80) is made of a plurality of interconnecting sections (82;84;86) with mating surfaces.

28. The implant according to one of the claims 1 to 27, characterized in that it is in combination with a discrete spacer (120) comprising a piece of allogenic bone conforming in size and shape with a second portion of an end plate of a vertebra and having a wedge-shaped profile, wherein the top and bottom surfaces (14;16) of the second member are substantially smooth and regions between top and bottom surfaces (14;16) and anterior and lateral sides (26;28) of the spacer (120) have curved edges (30) to facilitate implantation of the spacer (120).

FIG 1

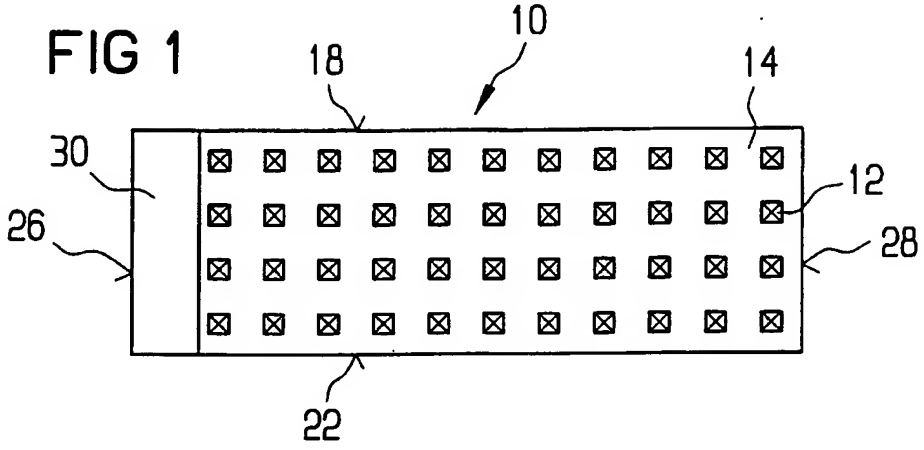


FIG 2

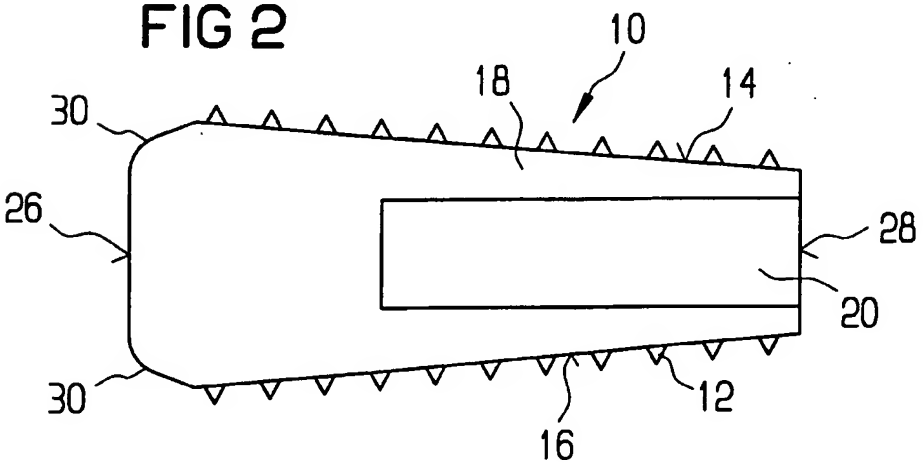


FIG 3

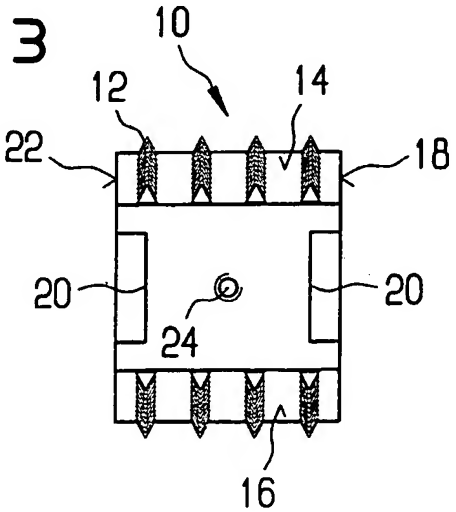


FIG 4

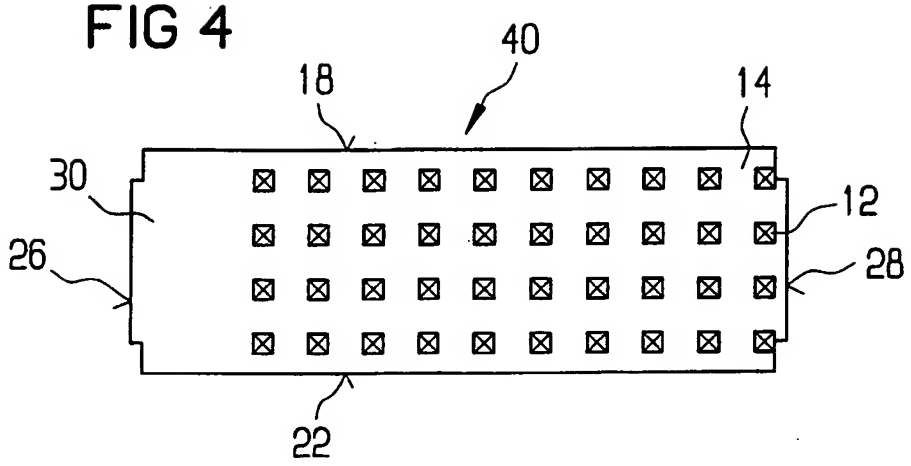


FIG 5

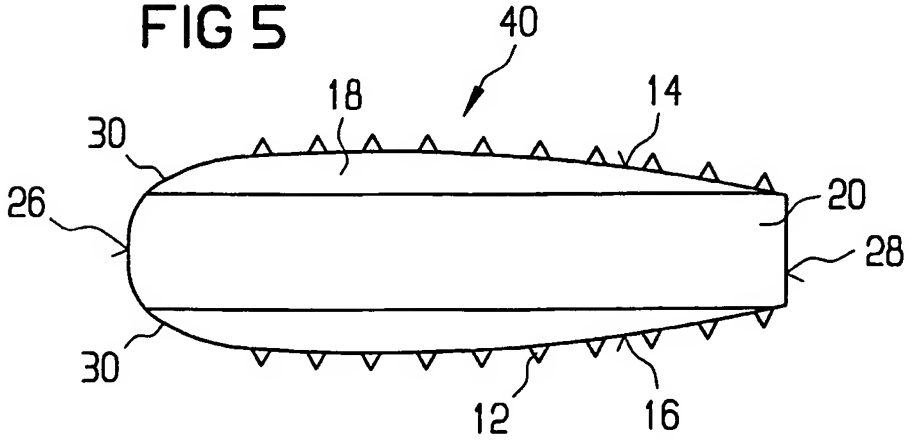


FIG 6

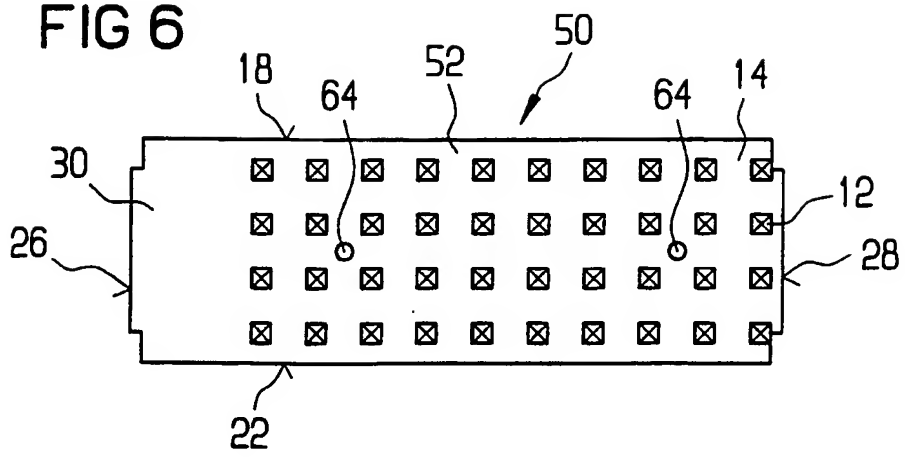


FIG 7

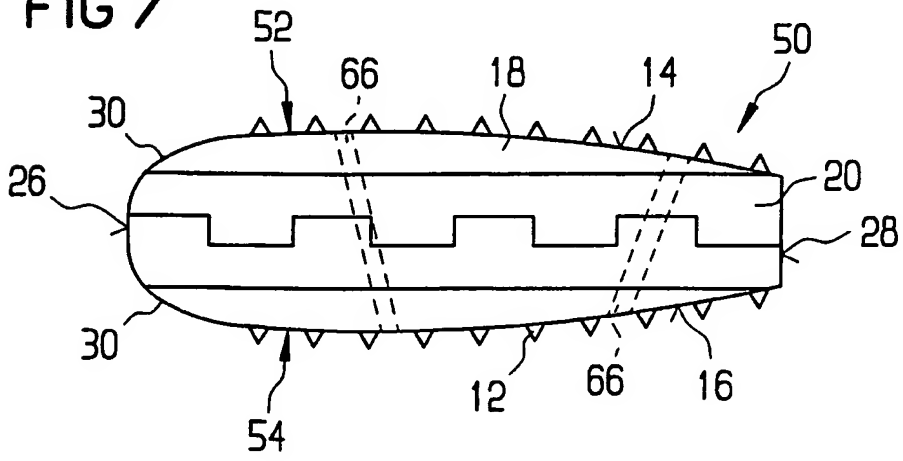


FIG 8A

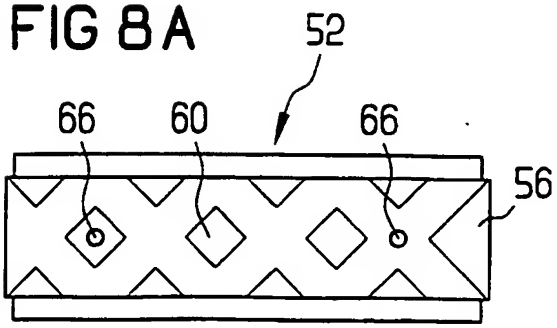


FIG 8B

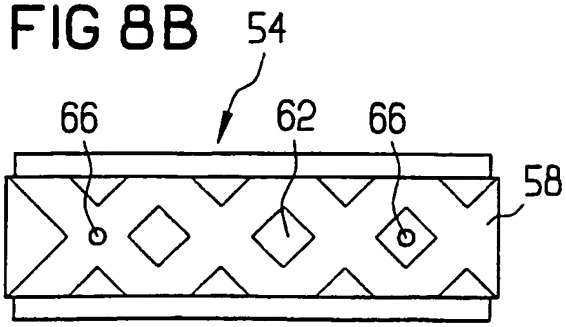


FIG 9

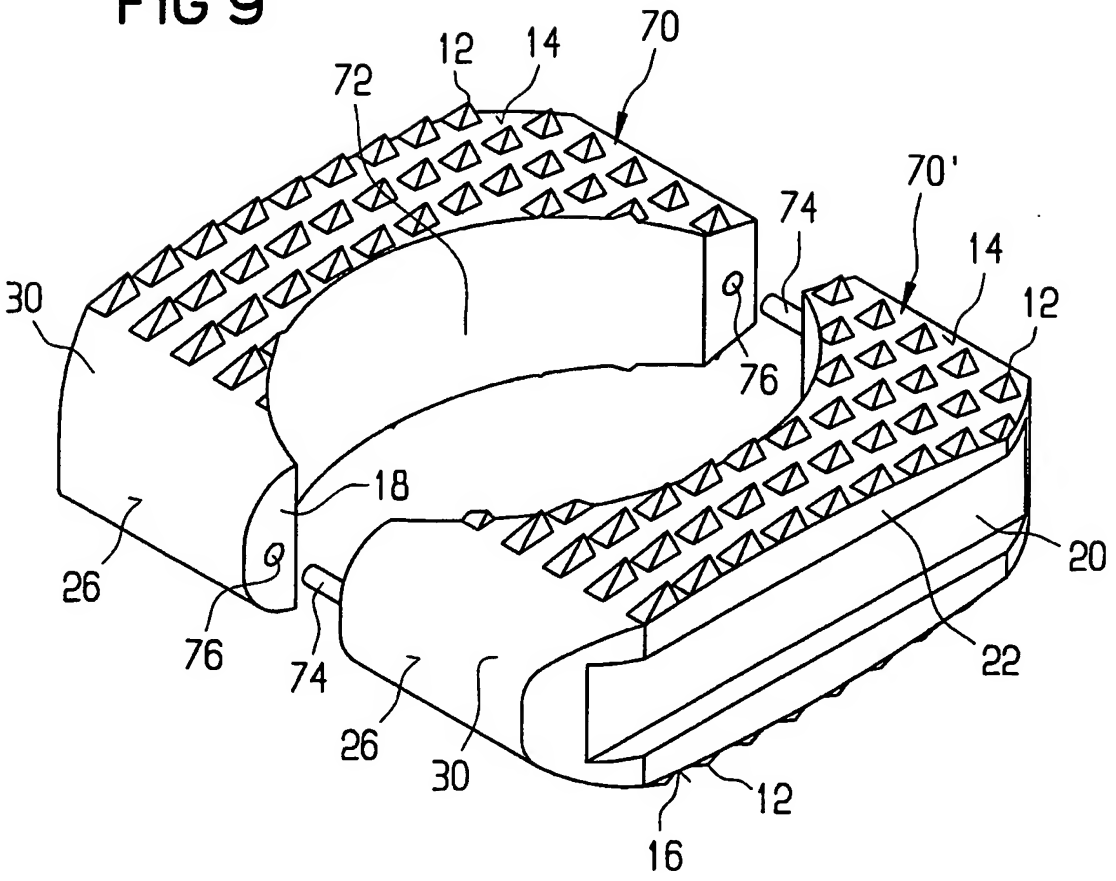


FIG 10A

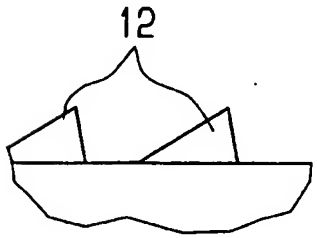


FIG 10B

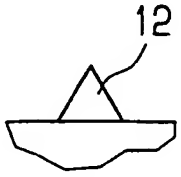


FIG 11

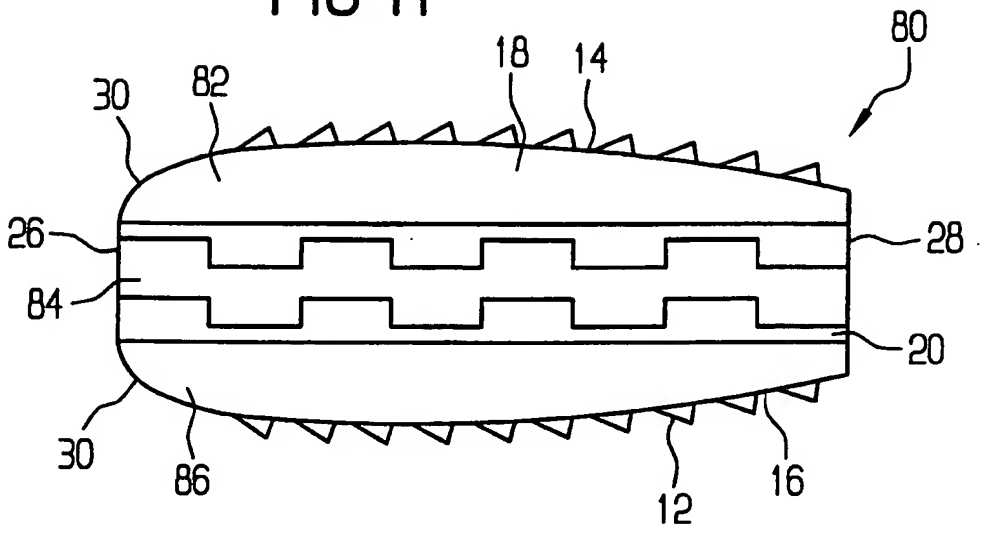


FIG 15

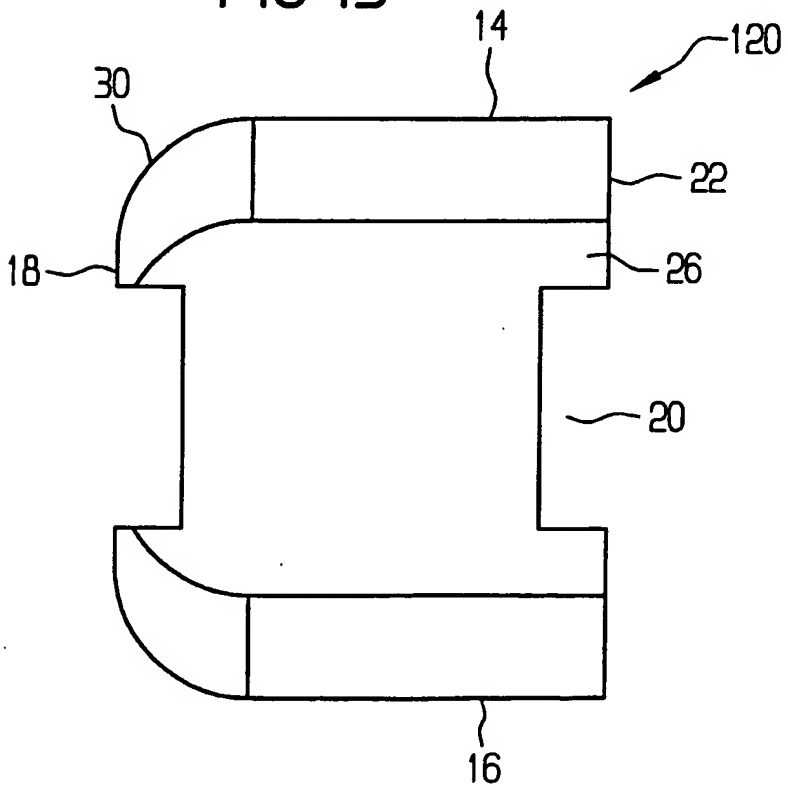


FIG 13

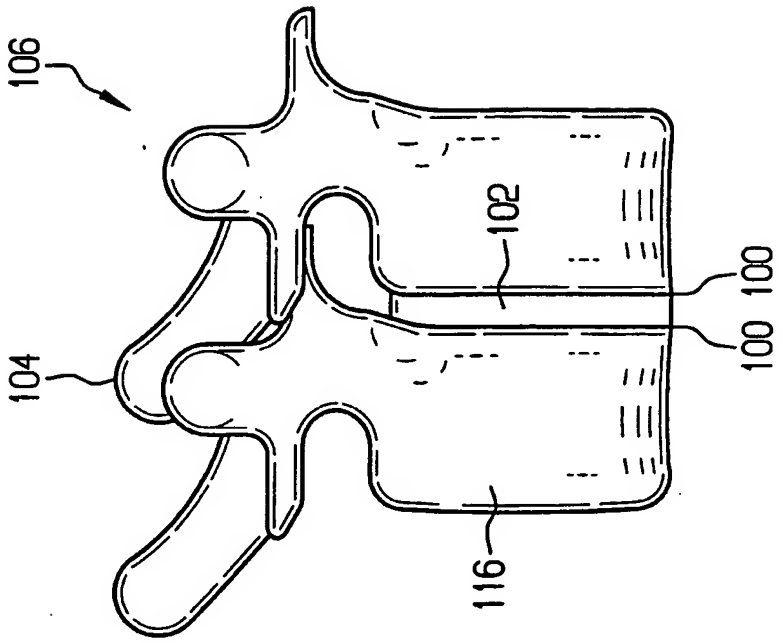


FIG 12

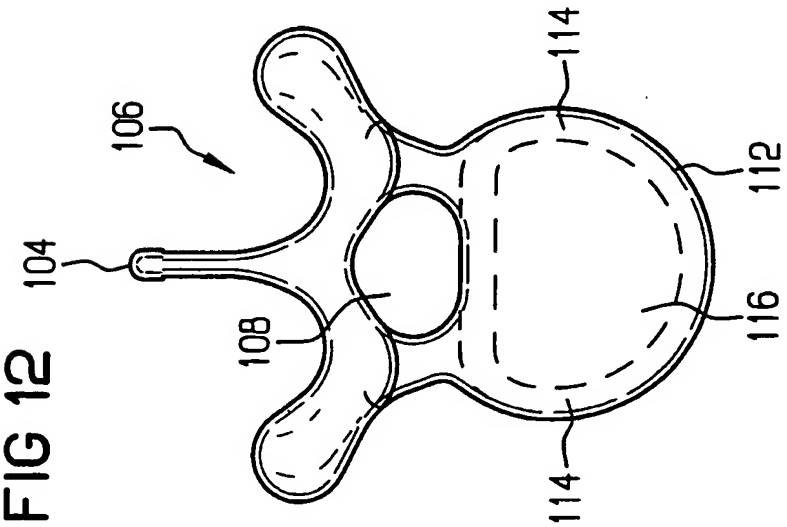
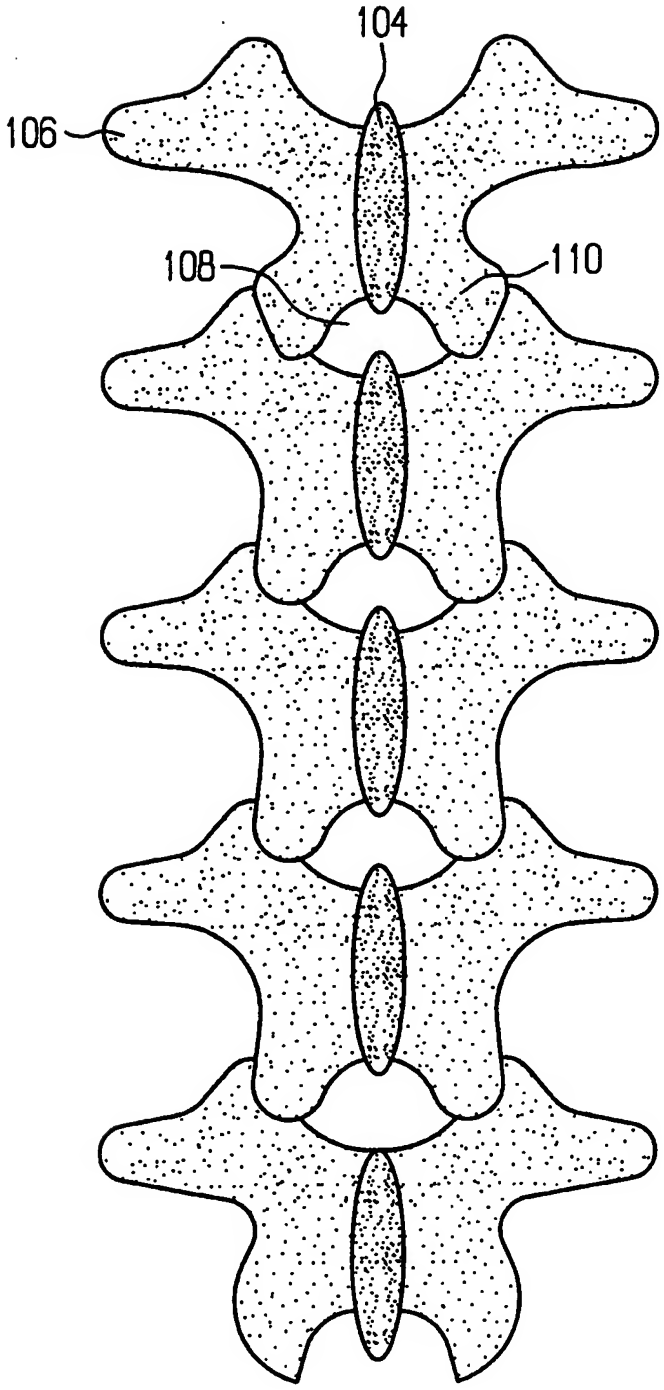


FIG 14



INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/05541

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 95 15133 A (CALCITEK INC) 8 June 1995 (1995-06-08) page 3, line 24 - line 31; figures 1-9	1,2,5-7, 12-15 3,4, 8-11,16, 28
Y	EP 0 646 366 A (ACROMED CORP) 5 April 1995 (1995-04-05) column 3, line 42 -column 4, line 38; figures	3,4,8,16
Y	WO 95 08964 A (BRANTIGAN JOHN W) 6 April 1995 (1995-04-06) the whole document	9-11

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 December 1999	11/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Klein, C

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INTERNATIONAL SEARCH REPORT

national Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 5 514 180 A (HEGGENESS MICHAEL H ET AL) 7 May 1996 (1996-05-07) column 1, line 44 - line 57 column 4, line 16 - line 51 column 10, line 36 - line 47; figures	1,12-15, 24-26
A	FR 2 717 068 A (BIOMAT) 15 September 1995 (1995-09-15) page 1, line 17 - line 26; figures 1-11	1,5,6,8, 12
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